



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

DX

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

08/716,169 12/17/96 ANDERTON S 961125

HM12/0802
WEBB ZIESENHEIM BRUENING LOGSDON
ORKIN & HANSON
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH PA 15219-1818

EXAMINER

NOLAN, P

ART UNIT	PAPER NUMBER
----------	--------------

1644

31

DATE MAILED: 08/02/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/716,169

Applicant(s)

ANDERTON et al.

Examiner

NOLAN

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 5-26-99.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 3-6, 17-18, 21 and 22 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3-6, 17-18, 21 and 22 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Part III DETAILED ACTION

1. This application is a 371 of PCT/NL95/00108.
2. Claims 1, 3-6, 17-18 and 21-22 are pending.
3. The request filed on 1-29-99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/716,169 is acceptable and a CPA has been established. An action on the CPA follows.
4. Claims 17-18 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 appears to be identical in scope with claim 1. If applicant regards claim 1 as closed, than amendment of claim 21 is required. Furthermore, claim 17 appears to be identical to claim 17. A composition claim requires two products. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-4 and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by European Patent 262,710 (AL), of record.

The '710 patent teaches a peptide, Antigen A, (i.e. hsp65 of *M. bovis* BCG, which Applicant recites is identical to hsp65 of *M. tuberculosis*), wherein amino acid sequence 171-240 has 5 consecutive amino acids that are identical to the human stress homologue, (i.e. peptide 171-175 of hsp65 of *M. bovis* BCG is identical to peptide 197-201 of the human stress protein) (page 7, in particular). The '710 patent also teaches the use of the peptide in diagnostic as well as pharmaceutical compositions (page 7, lines 38-44, in particular).

The prior art teachings anticipate the claimed invention. It is noted that this rejection is being reinstated because claim 1 is interpreted as being open.

6. Claims 1, 3-6, 17-18 and 21-22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Canadian Patent 2,072,009 (AL).

The '009 patent teaches a peptide derived from a microbe which has 5 consecutive amino acid sequences identical to the mammalian stress homologue shown in SEQ ID NO. 1 in positions 91-95 (page 26, in particular). In addition the '009 patent teaches the peptide was generated by cleaving the full length protein with trypsin and the fragments were fractionated by HPLC (page 23) (i.e. when the fragments were trypsinized and fractionated it is art recognized that they would be in solutions therefore meeting the limitations of a composition claim). Furthermore it would be an inherent property of the disclosed peptide to have a T cell epitope since the 5 amino acid between Applicant's illustrated species in the specification and the prior art peptide are identical.

The prior art teachings anticipate the claimed invention.

Applicant's arguments filed 5-26-99 have been fully considered but are not found persuasive.

Applicant argues that since the full length protein disclosed on page 27 of the '009 patent teaches a PHE amino acid in place of a THR amino acid, the trypsin digested peptide was in error and not appropriate prior art.

However, the peptide was made and used by the '009 patent to successfully create an oligonucleotide which was used to probe a cDNA library to pull out the full length sequence. Furthermore Applicant is invited to consider two possible reasons as to why the full length sequence was not identical to the peptide disclosed on page 26, (1) sequencing error, as documented by Naeve et al., automated sequencing of upto 400-500 bases regularly include a sequencing error rate of 1-5%, (see 2nd column, page 448), so a change of one or two nucleic acids could reasonably account for a PHE to THR switch; (2) Threonine and phenylalanine are considered conservative substitutions of each other, so it is reasonable to consider that the peptide sequence and the full length protein sequence are alleles of each other, or could be strain variants, since the change of a PHE for a THR would not be expected to effect the biological function of a 212 amino acid protein.

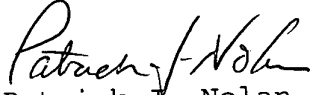
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any

Serial Number 08/716,169
Art Unit: 1644

4

inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, appearing to read "Patrick J. Nolan".

Patrick J. Nolan, Ph.D.
Patent Examiner, Group 1640
July 30, 1999